UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVARTIS PHARMA AG, Plaintiff, v. AMGEN, INC., Defendant.	Case No.: 19-CV-2993 **FIRST AMENDED COMPLAINT**

Novartis Pharma AG ("Novartis Pharma"), by and through its undersigned attorneys, brings this action against Amgen, Inc. ("Amgen"), to obtain a judgment (i) declaring that Novartis Pharma has not breached its Exclusive License and Collaboration Agreement with Amgen, dated August 28, 2015, as amended (the "2015 Agreement"); (ii) declaring that Novartis Pharma has not breached its Collaboration Agreement with Amgen, dated April 21, 2017 (the "2017 Agreement" and, collectively with the 2015 Agreement, the "Agreements"); (iii) declaring that any breach of either Agreement was not "material"; (iv) declaring that any breach of either Agreement has been cured; (v) declaring that Amgen's purported termination of the Agreements is invalid and of no force and effect; and (vi) for compensatory damages for Amgen's breach of contract—for failing to pay in full an invoice for commercialization costs above a contractual cap, which were incurred by Novartis Pharma in the fourth quarter 2018—in an amount of $56,178,633.66, plus interest, costs and fees.

1. Since 2015, Novartis Pharma and Amgen have collaborated in connection with the development and commercialization of Aimovig (erenumab), a groundbreaking migraine prevention therapy. Aimovig received regulatory approval in the United States in May

2018. In the short time since it has been launched in the U.S., the product has become a runaway success and the number of patients being treated has vastly exceeded what Amgen and Novartis Pharma projected. Aimovig has found the same success across the globe, gaining European Union approval in July 2018, and product launches in 27 other countries.

2. Novartis Pharma brings this action to prevent Amgen from unjustifiably terminating Novartis Pharma's collaboration rights under the Agreements in the wake of Aimovig's early success. Amgen was originally happy to collaborate with Novartis Pharma concerning the development and commercialization of Aimovig, especially since the collaboration required Novartis Pharma to bring unique capabilities, including its well-established neuroscience field force footprint and market experience, and to make substantial upfront investments and significant milestone payments to Amgen. Having reaped these benefits, which measure in the hundreds of millions of dollars, Amgen now wants to keep the Aimovig profits for itself and deprive Novartis Pharma of its contractual right to share in the product's success and recoup its significant investments.

3. Relying on the pretext that the Agreements have been breached because a separate and independent affiliate of Novartis Pharma is providing contract manufacturing services to a company that might one day launch another migraine product, Amgen issued a formal notice of termination (the "Notice of Termination") dated April 2, 2019, which purports to seek termination of the Agreements. Amgen has no right to do so.

4. Amgen bases its termination of both Agreements on a "Distracting Program" provision in the 2015 Agreement that restricts the parties from participating in certain other drug programs that would "distract" their focus away from Aimovig. However, the 2017 Agreement, which covers the highly valuable U.S. market, does not even contain a "Distracting

Program" provision, making Amgen's purported termination of that Agreement completely untenable. Amgen's purpose is all too apparent. On the heels of Aimovig's successful U.S. launch, Amgen wants to cut Novartis Pharma out of the future sales of Aimovig in the U.S. Novartis Pharma made significant and substantial contributions to Aimovig's U.S. launch and the 2017 Agreement affords Amgen no basis to simply discard Novartis Pharma's future rights in U.S. sales.

5. Amgen's purported termination of the 2015 Agreement is likewise untenable. The immaterial contract manufacturing services being provided by an entity that is part of a separate division from Novartis Pharma are not "distracting" Novartis Pharma from developing and commercializing Aimovig in any way, as Novartis Pharma's enormous investments into Aimovig and the successful launches of Aimovig to date attest. In any event, the program about which Amgen has complained is being terminated.

6. By this action, Novartis Pharma seeks declarations invalidating Amgen's attempt to terminate the Agreements. These declarations are necessary to prevent Amgen from reaping the windfall of Novartis Pharma's financial and other contributions, without having to share the fruits of the parties' collaboration.

7. In addition to the foregoing, Amgen is itself in breach of the 2017 Agreement. In particular, under the 2017 Agreement, the parties agreed to share commercialization costs. The 2017 Agreement provides that for calendar year 2018, Novartis Pharma was responsible for all commercialization costs, up to a specified cap. The Agreement further provides that Amgen is responsible for any and all commercialization costs above the Novartis Pharma cap. In 2018, Novartis Pharma incurred commercialization costs in support of Aimovig in an amount that exceeded the cap. Accordingly, on March 22, 2019, Novartis

Pharma, through Novartis Pharmaceuticals Corporation, issued Amgen an invoice for the amount Novartis Pharma paid in commercialization costs over and above the cap in 2018. On April 22, 2019, Amgen made a partial payment of the invoiced amount. As of the date of this Amended Complaint, Amgen has not paid the invoice in full. Accordingly, Novartis Pharma seeks compensatory damages from Amgen in the amount of $56,178,633.66, plus interest, costs, and fees, for Amgen's breach of contract.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because Novartis Pharma is a citizen of a foreign state and Amgen is a citizen of California, and the amount in controversy—if Amgen were successful in terminating the 2015 and/or 2017 Agreements and by virtue of Amgen's breach of the 2017 Agreement—vastly exceeds $75,000, exclusive of costs and interest.

9. This Court has personal jurisdiction over Amgen because Amgen, upon information and belief, conducts business in the State of New York and within this district.

10. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1391(d).

11. In addition, the Agreements provide that Amgen and Novartis Pharma each consent to the exclusive jurisdiction of the state and federal courts of the State of New York for any matter arising out of or relating to the Agreements.

12. An actual case or controversy has arisen between the parties. Amgen issued a Notice of Termination dated April 2, 2019, asserting a right to terminate the Agreements. Novartis Pharma disputes that there is any basis to terminate either the 2015 Agreement or the 2017 Agreement. The declaratory judgments sought in this case will settle the legal relations between Novartis Pharma and Amgen and will resolve the uncertainty created by Amgen's attempt to terminate the Agreements. In addition, on March 22, 2019, Novartis Pharma

issued Amgen an invoice for commercialization costs in excess of a contractual cap, which were due and owing under the 2017 Agreement. Amgen had until April 22, 2019, to pay the invoice. On April 22, 2019, Amgen made a partial payment, but as of the date of this Amended Complaint, Amgen has not paid the invoiced amount in full. Amgen is therefore presently in breach of the 2017 Agreement.

THE PARTIES

13. Novartis Pharma is a Swiss corporation having its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

14. Amgen is a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California.

ALLEGATIONS

I. THE NOVARTIS-AMGEN RELATIONSHIP AND THE SUCCESS OF AIMOVIG

15. Upon information and belief, prior to August 28, 2015, Amgen owned or controlled all rights to Aimovig, a human monoclonal antibody against the calcitonin gene-related peptide ("CGRP") receptor designed for the prevention of migraines.

16. Aimovig is in the vanguard of a whole new class of therapies: it is the first FDA- and European Medicines Agency-approved CGRP-targeted therapy for the prevention of migraines in adults. With Aimovig, patients responding to the medicine achieve a significant decrease in both the frequency and severity of migraines, leading to more normal and productive lives as a result. There has been a strong market demand for this effective treatment and, in the short time since the U.S. launch, approximately 210,000 patients have already benefited from Aimovig. The product has since launched in 27 more countries and approximately 20,000 patients outside the U.S. have also benefited. The product will also be launched in 33 additional countries by the end of 2020.

17. Amgen determined that it wanted the assistance of an experienced collaboration partner for the development and commercialization of Aimovig around the world. Novartis Pharma has over 70 years of experience in the field of neuroscience. Years before Aimovig was approved anywhere for use by patients, Amgen and Novartis Pharma entered into their first collaboration agreement for Aimovig, referred to here as the 2015 Agreement. In exchange for the right to commercialize Aimovig worldwide (apart from the U.S., Canada and Japan), the 2015 Agreement required Novartis Pharma to make substantial investments in development, approval and commercialization of Aimovig. Under the 2015 Agreement, Amgen is also entitled to share in the profits of these worldwide sales in the form of a royalty. To date, Novartis Pharma has invested approximately $340 million (including significant milestone payments to Amgen) and the full-time effort of many employees pursuant to the 2015 Agreement.

18. Novartis Pharma made these investments confident that it would contribute to a successful approval and launch of Aimovig in many markets worldwide. The income from the sale of Aimovig in those markets is Novartis Pharma's sole return on its investment pursuant to the 2015 Agreement.

19. Aimovig has recently launched in 27 markets outside of the U.S. to date, and launches in many more markets, including 19 planned for 2019, are currently underway. The timing is significant. Amgen is seeking to terminate the 2015 Agreement at a time when it has reaped the substantial benefit of the parties' collaboration, but before Novartis Pharma receives anything in return.

20. Amgen and Novartis Pharma entered into a second collaboration, referred to here as the 2017 Agreement. Pursuant to the 2017 Agreement, Amgen granted Novartis

Pharma co-commercialization rights for Aimovig in the U.S., a large and important market. Faced with the expensive and daunting task of launching a new drug in the U.S., Amgen wanted to draw upon the resources and experience of Novartis Pharma. In support of the U.S. launch, Novartis Pharma invested approximately $530 million (again, including significant milestone payments to Amgen) and the substantial time and effort of Novartis employees. Here again, Novartis Pharma's sole return for these investments comes from a share in Amgen's profits from sales of Aimovig in the U.S. Aimovig launched in the U.S. in May 2018, beating its main competitors to the market. The launch was successful and patient demand has far exceeded both parties' expectations and has been described as the most successful biologic launch in the U.S. to date. Amgen and Novartis, working together, have achieved this success despite the quick launch of two competitors in the U.S. market: Teva Pharmaceutical Industries Ltd.'s biologic, Ajovy, and Eli Lilly and Company's biologic, Emgality, both of which obtained U.S. regulatory approval in September 2018, approximately four months after Aimovig obtained approval.

II. AMGEN'S ATTEMPT TO TERMINATE THE AGREEMENTS

21. While Novartis Pharma has contractually shared in Aimovig's initial success during the short time that the product has been available, Amgen now seeks to terminate Novartis Pharma's rights under the 2017 Agreement, before Novartis Pharma has come close to earning a return on its investment.

22. In sum, due in no small part to Novartis Pharma's meaningful efforts and investments—including Novartis Pharma's efforts to accelerate the launch in many markets, bringing value to new patients—Aimovig is already succeeding in the U.S. and in the 27 other markets where it has been launched, and is poised to be a successful and remunerative therapy for years into the future both in the U.S. and internationally. Aimovig appears likely to generate a considerable return on the substantial investments required to bring it to market. Amgen no

longer wishes to honor its contractual obligations to share this upside with Novartis Pharma and has purported to terminate the Agreements. If successful, Amgen would achieve a remarkable windfall: it would retain the entirety of Novartis Pharma's investment without having to share the profits with its partner.

A. AMGEN'S PRETEXT FOR TERMINATION

23. During the summer of 2018, Novartis Pharma personnel learned that, pursuant to a contract manufacturing agreement that became effective on May 4, 2015 (the "Alder CMA"), Sandoz GmbH (Austria) ("Sandoz CMO") manufactures a compound called ALD403 (eptinezumab) for Alder Biopharmaceuticals ("Alder") at a facility in Austria.

24. Sandoz CMO is an indirect subsidiary of Sandoz Inc., which is indirectly owned by the same indirect parent of Novartis Pharma.

25. ALD403 is being developed for the treatment of migraines and has not been approved for sale to patients. If it eventually launches, ALD403 will be the fourth entrant on the market.

26. Upon information and belief, ALD403 differs significantly from, and will not fully compete with, Aimovig. Specifically, ALD403 functions with a different mechanism of action than Aimovig. It is administered by intravenous (IV) injection which must be performed by a medical professional at a physician's office, unlike Aimovig, which patients may self-administer at home.

27. Shortly after learning of Sandoz CMO's involvement with Alder, Novartis Pharma advised Amgen of the existence of the relationship in good faith and in the interest of maintaining an open collaboration.

28. On November 29, 2018, pursuant to the terms of the Agreements, Amgen sent Novartis Pharma a formal notice of material breach (the "Notice of Material Breach").

Amgen claimed that the existence of the Alder CMA caused Novartis Pharma to be in material breach of both the 2015 Agreement and the 2017 Agreement.

29. On January 24, 2019, pursuant to Sections 15.2.2 and 14.2.1 of the respective Agreements, Novartis Pharma responded to Amgen's Notice of Material Breach. Novartis Pharma disputed the existence of any breach, disputed the materiality of any breach, and explained that any supposed breach had been cured.

30. Amgen nevertheless issued a Notice of Termination dated April 2, 2019.

31. Also on April 2, 2019, in response to the Notice of Termination, Novartis Pharma issued a Notice of Disagreement in Good Faith in accordance with the Agreements.

32. Pursuant to Section 15.2.2 of the 2015 Agreement and Section 14.2.1 of the 2017 Agreement, both Agreements remain in full force and effect pending a final judicial resolution of the dispute between the parties.

B. RELEVANT CONTRACTUAL LANGUAGE

33. The 2015 Agreement, at Section 7.2, prohibits either Party, itself or through its Affiliates, from engaging in a so-called "Distracting Program":

> Activities Outside the Collaboration. Except as set forth in Sections 7.3 (Post-Effective Date Affiliates) and 7.4 ([*] Divestiture), during the Term, neither Party shall, itself or through its Affiliates, directly or indirectly conduct or participate in, or advise, assist or enable a Third Party to conduct or participate in, any Distracting Program.[1]

34. The 2017 Agreement does not include a Distracting Program clause analogous to Section 7.2 of the 2015 Agreement.

35. A Distracting Program is defined in Section 1.37 of the 2015 Agreement:

[1] For purposes of this pleading, Novartis Pharma has adopted the redactions (denoted by "[*]") to the Agreements that Amgen applied when it filed the Agreements as exhibits to its Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017.

> *"Distracting Program"* means the clinical development, commercialization or manufacture of any Distracting Product.

36. In its Notice of Material Breach, Amgen asserts that ALD403 falls within the definition of Distracting Product.

37. Sections 15.2.2 of the 2015 Agreement and Section 14.2.1 of the 2017 Agreement are identical. They state:

> *Termination for Breach.* If either Party believes that the other Party is in material breach of this Agreement, then such Party may deliver notice of such material breach (specifying the nature of the breach in reasonable detail) to the other Party. If the breaching Party (or its Affiliate) fails to cure such material breach within [*] days after the receipt of such notice (or [*] days with respect to any failure to pay amounts due hereunder), then the other Party shall be permitted to terminate this Agreement by written notice given within [*] days after the end of such cure period and effective upon delivery; *provided, however*, if the breaching Party notifies the other Party within such [*] day period that it disagrees in good faith with such asserted basis for termination, this Agreement shall not terminate unless and until the matter has been finally resolved in accordance with Section [15.3/16.3] (Governing Law; Jurisdiction); *provided further* that if such dispute relates to payment, the cure period will only apply with respect to payment of disputed amounts, and not with respect to undisputed amounts.

38. "Material breach" is not defined in either the 2015 Agreement or the 2017 Agreement.

C. NOVARTIS PHARMA HAS NOT BREACHED THE 2015 AGREEMENT

39. In its Notice of Material Breach, Amgen asserted that the Alder CMA materially breached the 2015 Agreement. In particular, Amgen asserted that Alder's product was a "Distracting Product" as defined in Section 1.36 of the 2015 Agreement, and the development, commercialization or manufacture of Alder's product is a "Distracting Program" as defined in Section 1.37 of the 2015 Agreement. Amgen contends that, as such, Novartis Pharma, by virtue of the Alder CMA, has violated Section 7.2 of the 2015 Agreement.

40. However, the immaterial contract manufacturing services being provided by an entity that is part of a separate division from Novartis Pharma are not "distracting"

Novartis Pharma from developing and commercializing Aimovig. To the contrary, Novartis Pharma has made enormous investments into Aimovig and contributed significantly to the successful launches of Aimovig to date. It was not involved in the Alder CMA and could not have been "distracted" by it.

41. Moreover, despite Amgen's claim to the contrary, the contractual language makes clear that Novartis Pharma has not breached the 2015 Agreement. Section 7.2 of the 2015 Agreement states that neither party shall participate in a Distracting Program "itself or through its Affiliates." Novartis Pharma plainly did not enter into the Alder CMA "itself" here, nor did it do so "through" Sandoz CMO. Sandoz CMO acted alone, not at the direction or instruction of Novartis Pharma. In addition, although Novartis Pharma and Sandoz CMO are technically "Affiliates," they are "sister" companies, not direct or indirect subsidiaries of one another. Novartis Pharma is therefore not capable of causing something to happen "through" Sandoz CMO.

42. In addition, Sandoz CMO was expressly excluded from the definition of "Affiliate" in the 2015 Agreement. Thus, when Novartis Pharma and Amgen entered into the 2015 Agreement a few months after Sandoz CMO entered into the Alder CMA, the Alder CMA was, by definition, not a Distracting Program under the 2015 Agreement. On April 21, 2017, Novartis Pharma and Amgen entered into Amendment No. 2 to the 2015 Agreement, pursuant to which Sandoz CMO was included as an Affiliate for purposes of the 2015 Agreement. That event did not retroactively transform Sandoz CMO's entry into the Alder CMA *two years earlier* into an action by Novartis Pharma "through" an Affiliate.

D. NOVARTIS PHARMA HAS NOT BREACHED THE 2017 AGREEMENT

43. In its Notice of Material Breach, Amgen maintained that the Alder CMA is a material breach of the 2017 Agreement. Amgen does not point to any specific provision of

the 2017 Agreement that it claims has been breached. Instead, Amgen's Notice of Material Breach states, without any support, that Section 7.2 of the 2015 Agreement somehow applies to the 2017 Agreement. Amgen's claim is at odds with the plain language of the Agreements.

44. The 2017 Agreement does not incorporate the "Distracting Program" restriction set forth in Section 7.2 of the 2015 Agreement. As made clear by the 2015 Agreement, the Parties knew how to include such a provision when they wanted to, but they did not do so in the 2017 Agreement.

45. There is no applicable cross-termination provision in either the 2015 Agreement or the 2017 Agreement. Even assuming that Amgen had a basis to terminate the 2015 Agreement—which it does not—such a termination does not affect the 2017 Agreement and does not provide Amgen with a basis to terminate the 2017 Agreement.

E. ANY BREACH BY NOVARTIS PHARMA WAS NOT MATERIAL

46. Pursuant to Section 15.2.2 of the 2015 Agreement and 14.2.1 of the 2017 Agreement, any right to terminate the Agreements requires a "material breach," a term not defined in either Agreement.

47. Even assuming that the Alder CMA was a breach of either Agreement, it was not a material breach and does not give rise to a termination right.

48. Amgen has not been and will not be deprived of the benefit it reasonably expects under the Agreements. To the contrary, the central objectives of the Agreements have been and continue to be achieved, contributing to the overwhelming success of Aimovig thus far in the market. The existence of the Alder CMA does not change that fact.

49. The scope of the Alder CMA is insignificant in comparison to the size and scope of the Novartis Pharma-Amgen collaboration. Under the Alder CMA, Sandoz CMO is a contract manufacturer, not a co-developer and not a co-commercialization partner.

50. Alder's product has not been approved and it is not currently on the market. Under the best of circumstances, it would be the fourth product to enter the market long after Aimovig has been well established.

51. Sandoz CMO's services have not provided Alder with any unique advantage; other companies could have provided the same manufacturing services to Alder.

52. Upon information and belief, the manufacturing services provided under the Alder CMA are based on Alder's technology, which is a markedly different technology than what is used for Aimovig.

53. Alder has not benefitted from any Amgen confidential information. In fact, pursuant to the 2015 and 2017 Agreements, Novartis Pharma has little, if any, information about Amgen's manufacturing process. To the extent that Novartis Pharma has any such information, firewalls are in place that prevent any information from the Novartis Pharma-Amgen collaboration from reaching personnel involved in the Alder CMA.

54. The forfeiture by, and prejudice to, Novartis Pharma if Amgen were permitted to terminate the Agreements would be enormous, particularly given Novartis Pharma's substantial investment in the Aimovig program and the fact that virtually none of that investment has been recouped at this stage of the parties' collaboration.

F. ANY SUPPOSED BREACH BY NOVARTIS PHARMA HAS BEEN CURED

55. Pursuant to Section 15.2.2 of the 2015 Agreement and Section 14.2.1 of the 2017 Agreement—the "Termination for Breach" provisions—the "breaching Party (or its Affiliate)" has an opportunity to cure any material breach within a certain number of days of receiving the notice of material breach. Only if the breaching party fails to cure the breach is the other party permitted to terminate the relevant agreement.

56. Here, effective January 1, 2019—well within the amount of time allotted in the Agreements from the date Novartis Pharma received Amgen's Notice of Material Breach—Sandoz CMO and Alder entered into an agreement by which the Alder CMA will be terminated (the "Termination Agreement").

57. The termination of a biologic contract manufacturing agreement necessitates a complex technology transfer that spans an extended period. As a result, under the Termination Agreement, Sandoz CMO is required to continue to provide production capacity to Alder in the Sandoz CMO facility for three to five years, but with significant financial incentives available to Alder if it ends the relationship sooner.

58. Because Sandoz CMO has entered into an agreement to terminate the Alder CMA, any alleged breach of the 2015 and 2017 Agreements has been effectively cured.

III. AMGEN HAS BREACHED THE 2017 COLLABORATION AGREEMENT

59. Under the 2017 Agreement, the parties agreed to share commercialization costs. The 2017 Agreement lays out specific cost allocations for Novartis Pharma for 2017 and 2018, the first two years of the parties' collaboration, after which point the parties agreed to split the commercialization costs equally.

60. The 2017 Agreement provides that for calendar year 2018, Novartis Pharma was responsible for all commercialization costs, up to a specified cap. The Agreement further provides that Amgen is responsible for any and all commercialization costs above the Novartis Pharma cap.

61. In particular, Section 8.6.1.5 of the 2017 Agreement provides in relevant part:

> *Allocation of Recoveries, Development Costs and Program Costs*. Each Party shall account for Program Costs and Development Costs in accordance with its Accounting Standards. Except as otherwise set forth herein: [. . .] **for the**

> **Calendar Year 2018** only, (i) **Novartis shall pay one hundred percent (100%) of Commercialization Costs up to a cap of [*] in the aggregate**, inclusive of a [*] payment to Amgen on or prior to [*] (as a contribution toward [*]), provided that Novartis shall have the right to prorate such payments over the four (4) Calendar Quarters in 2018, and (ii) **Amgen shall be responsible for any and all Commercialization Costs in Calendar Year 2018 above the [*] [cap amount] in Commercialization Costs paid by Novartis.**

Emphasis added.

62. The Commercialization Costs cap was the product of negotiations between the parties before the 2017 Agreement was executed. In particular, Amgen wanted to maximize Novartis Pharma's upfront payments under the 2017 Agreement. The parties originally discussed no upfront payment, a lower initial milestone payment and no cap for 2018. Over the course of the negotiations, Novartis Pharma agreed to include an upfront payment to Amgen and an increased milestone payment to Amgen, in exchange for a cap of its commercialization costs for 2018.

63. In 2018, commercialization costs incurred by Novartis Pharma exceeded the agreed-upon cap. These costs were attributable to, among other things, direct to consumer advertising, the development, training and deployment of a field force, support for patient services and other necessary and reasonable expenses to commercialize and launch Aimovig during 2018.

64. At all relevant times in 2018, Amgen was aware that the commercialization efforts costs exceeded Novartis Pharma's capped amount set forth in Section 8.6.1.5 of the 2017 Agreement.

65. Pursuant to Section 8.6.1.5 of the 2017 Agreement, Novartis Pharma is responsible for the capped amount and Amgen is responsible for the difference.

66. Amgen has acknowledged the existence and applicability of the cap at various points in the parties' discussions.

67. On March 22, 2019, Novartis Pharma issued Amgen an invoice for the amount Novartis Pharma paid in commercialization costs over and above the cap in 2018.

68. Amgen had until April 22, 2019 to pay the invoice.

69. On April 22, 2019, Amgen made a partial payment of the invoiced amount.

70. As of the date of this Complaint, Amgen has not paid the invoiced amount, and still owes $56,178,633.66 to Novartis Pharma under the 2017 Agreement and pursuant to the March 22, 2019 invoice.

71. As a result, Amgen is in breach of the 2017 Agreement.

CLAIMS FOR RELIEF

COUNT I

(Declaratory Judgment of No Breach of the 2015 Agreement)

72. Novartis Pharma repeats the prior allegations of this complaint as if the same were made part of and fully set forth herein.

73. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 and 2202, this Court is authorized to issue a declaratory judgment.

74. The proper interpretation and application of the provisions of the 2015 Agreement to the case at hand, including whether there has been a breach of the 2015 Agreement, is a justiciable, present, and actual controversy between Novartis Pharma and Amgen.

75. The Alder CMA does not constitute a breach the 2015 Agreement.

76. The Alder CMA does not permit Amgen to terminate the 2015 Agreement.

77. Novartis Pharma seeks a declaration that it has not breached the 2015 Agreement and there is no basis to terminate the 2015 Agreement.

COUNT II

(Declaratory Judgment of No Breach of the 2017 Agreement)

78. Novartis Pharma repeats the prior allegations of this complaint as if the same were made part of and fully set forth herein.

79. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 and 2202, this Court is authorized to issue a declaratory judgment.

80. The proper interpretation and application of the provisions of the 2017 Agreement to the case at hand, including whether there has been a breach of the 2017 Agreement, is a justiciable, present, and actual controversy between Novartis Pharma and Amgen.

81. The Alder CMA does not constitute a breach of the 2017 Agreement.

82. The Alder CMA does not permit Amgen to terminate the 2017 Agreement.

83. Novartis Pharma seeks a declaration that it has not breached the 2017 Agreement and that there is no basis to terminate the 2017 Agreement.

COUNT III

(Declaratory Judgment that Any Breach of Either Agreement Was Not "Material")

84. Novartis Pharma repeats the prior allegations of this complaint as if the same were made part of and fully set forth herein.

85. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 and 2202, this Court is authorized to issue a declaratory judgment.

86. The proper interpretation and application of the provisions of the 2015 Agreement and 2017 Agreements to the case at hand, including whether there has been a material breach of the Agreements, is a justiciable, present, and actual controversy between Novartis Pharma and Amgen.

87. The Alder CMA does not constitute a "material breach" of the 2015 Agreement.

88. The Alder CMA does not constitute a "material breach" of the 2017 Agreement.

89. The Alder CMA does not permit Amgen to terminate either Agreement.

90. Novartis Pharma seeks a declaration that even if the Alder CMA constituted a breach of either of the Agreements, it did not constitute a "material breach" and there is no basis to terminate either the 2015 Agreement or the 2017 Agreement.

COUNT IV

(Declaratory Judgment that Any Breach of Either Agreement Has Been Cured)

91. Novartis Pharma repeats the prior allegations of this complaint as if the same were made part of and fully set forth herein.

92. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 and 2202, this Court is authorized to issue a declaratory judgment.

93. The proper interpretation and application of the provisions of the 2015 and 2017 Agreements to the case at hand, including whether any breach has been cured, is a justiciable, present, and actual controversy between Novartis Pharma and Amgen.

94. Any alleged breach of the 2015 and 2017 Agreements by virtue of the Alder CMA has been cured.

95. The Alder CMA does not permit Amgen to terminate either Agreement.

96. Novartis Pharma seeks a declaration that any supposed breach has been cured by virtue of the Termination Agreement entered into between Sandoz CMO and Alder and there is no basis to terminate either the 2015 Agreement or the 2017 Agreement.

COUNT V

(Breach of Contract)

97. Novartis Pharma repeats the prior allegations of this amended complaint as if the same were made part of and fully set forth herein.

98. Pursuant to Section 8.6.1.5 of the 2017 Agreement, for calendar year 2018, Novartis Pharma agreed to pay 100% of the commercialization costs, subject to a specified cap.

99. Also pursuant to Section 8.6.1.5, Amgen is required to pay any and all commercialization costs above Novartis Pharma's capped amount.

100. Novartis Pharma has performed under the contract, as it paid for its commercialization costs in calendar year 2018.

101. On March 22, 2019, Novartis Pharma issued Amgen an invoice for the amount Novartis Pharma paid in commercialization costs over and above the cap in 2018.

102. Pursuant to Section 8.6.4 of the 2017 Agreement, Amgen had until April 22, 2019 to pay the invoice.

103. On April 22, 2019, Amgen made a partial payment of the invoiced amount.

104. As of the date of this Complaint, Amgen has not paid the invoiced amount in full.

105. Amgen has therefore materially breached the 2017 Agreement.

106. Novartis Pharma has suffered damages in the amount of $56,178,633.66, plus interest, costs, and fees as a result of Amgen's breach.

PRAYER FOR RELIEF

WHEREFORE, Novartis Pharma respectfully requests that this Court enter an Order:

a. Declaring that Novartis Pharma has not breached the 2015 Agreement by virtue of Sandoz CMO's manufacturing services provided to Alder;

b. Declaring that Novartis Pharma has not breached the 2017 Agreement by virtue of Sandoz CMO's manufacturing services provided to Alder;

c. Declaring that any supposed breach of either Agreement was not "material";

d. Declaring that any supposed breach of either Agreement has been cured by virtue of the Termination Agreement entered into between Sandoz CMO and Alder;

e. Declaring that Amgen's purported termination of the Agreements is of no force and effect;

f. Entering a judgment in favor of Novartis Pharma and against Amgen for compensatory damages for Amgen's breach of contract, in an amount of $56,178,633.66, plus interest, costs and fees.

g. Awarding Novartis Pharma its costs associated with this action; and

h. Entering such other further relief to which Novartis Pharma may be entitled as a matter of law or equity, or which the Court determines to be just and proper.

Dated: New York, New York
July 16, 2019

ARNOLD & PORTER KAYE SCHOLER LLP

By: /s/ Jeffrey A. Fuisz

Jeffrey A. Fuisz
jeffrey.fuisz@arnoldporter.com
Amanda C. Croushore
amanda.croushore@arnoldporter.com
250 West 55th Street
New York, New York 10019-9710
(212) 836-8000

WHITE & CASE LLP

By: /s/ David G. Hille

David G. Hille
dhille@whitecase.com
Isaac Glassman
isaac.glassman@whitecase.com
Christopher Volpe
christopher.volpe@whitecase.com
1221 Avenue of the Americas
New York, New York 10020-1095
(212) 819-8200

Attorneys for Plaintiff Novartis Pharma AG